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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,577	02/12/2001	Irene E. Kochevar	10284-018001	9723

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EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER

BARRETT, THOMAS C

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,577

Applicant(s)

KOCHEVAR ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-20, 23-25 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-7, 9-20, 23-25 and 28 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 6-7, 9-11, 23 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Oz (WO 91/04073) as cited in Applicant's IDS. OZ discloses a method for tissue repair (e.g. page 10, lines 16-18), comprising: contacting a tissue, e.g. of a human (page 27, lines 19-21) in need of repair, and optionally a second tissue, with at least one photosensitizer agent to form a tissue-photosensitizer mixture; and applying electromagnetic energy at a wavelength of at least 488 nm (page 15 lines 10-11) to the tissue-photosensitizer mixture in a manner effective to produce cross linking of a protein in the tissue, wherein the tissue is not contacted with an exogenous cross-linkable substrate which is cross linked by the application of electromagnetic energy, thereby creating a tissue seal that repairs the tissue, wherein the repaired tissue has tensile strength. Rose Bengal or thiazine dyes such as methylene blue may be used (page 25, lines 15-21). The pressure limit of the seal is greater than 100 mm HG (e.g. page 12,

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lines 19-22). Please note that Oz does testing both with and without the exogenous substrate, and furthermore discloses, "It is possible that the tissue already has a natural soldering agent present so that such agent need not be added exogenously." (page 27, lines 24-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 5, 12-20 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz (WO 91/04073) as above, in view of Khadem (5,552,452). Oz discloses a method of tissue repair comprising the use of dyes and lasers without the use of exogenous proteins. However Oz does not disclose performing the method to repair corneal tissue. Khadem et al. teaches a method for adhering tissue comprising: contacting a tissue with a photosensitizer, creating a tissue-photosensitizer mixture,

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applying electromagnetic energy without more than a 1 degree rise in temperature (col. 3, line 67- col. 4, line 3), which therefore doesn't produce "substantial" thermal damage , and creating a tissue seal without contacting the tissue with an exogenous cross-linkable substrate (col. 7, lines 18-30). The method may be used for refractive surgery (col. 8, lines 3-8). The methods can be used on humans and in vivo or ex vivo (col. 15, lines 39-47).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of the use of laser and dyes for refractive surgery, as taught by Khadem et al., to the method as per Oz, because e.g. of it's improved burst strength (Oz- page 23, lines 24-28).

The combination of Oz and Khadem et al. fails to disclose the claimed specific application times, W/cm, and J/cm ranges. MPEP 2144.05 states:

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

The general conditions of the claims are disclosed in Oz and Khadem et al. Lasers are well known in the art to have controllable energy doses and irradiances, such as the commercial ones admitted to by the Applicant (pp 15-16). The optimum ranges of energy doses and irradiances can easily be found through routine

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experimentation. It would have been obvious to one of ordinary skill in the art to combine the teaching of routine experimentation to determine the optimum ranges of energy doses and irradiances, to a method for adhering tissue as per Khadem et al., in order to minimize tissue damage.

In addition, Khadem discloses, "Likewise, the application of the electromagnetic radiation will also be adapted to suit the particular circumstances of operation. It is generally envisioned that the time for performing a tissue closure procedure in accordance herewith will be less than five minutes in total." The optimum length of application of the electromagnetic radiation can easily be found through routine experimentation (col. 7, lines 31-45). It would have been obvious to one of ordinary skill in the art to combine the teaching of routine experimentation to determine the optimum length of application of the electromagnetic radiation, to a method for adhering tissue as per Khadem et al., in order to ensure tissue closure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

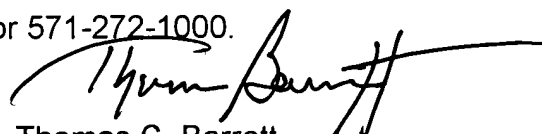
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached on Mon. -Fri. from 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Thomas C. Barrett